

HB

43

<TARGET><BILL>HB 43</BILL><SUBJECT>HB
43</SUBJECT><COMM>SHSS30</COMM></TARGET>

ALASKA STATE LEGISLATURE

Session

State Capitol, Rm. 418
Juneau, AK 99801
(907) 465-3892
Fax: (907) 465-6595

Interim

1500 W. Benson Blvd.
Anchorage, AK 99503
(907) 269-0234
Fax: (907) 269-0238



House Finance Committee

Dept. of Law
Finance Subcommittee
Chairman

Dept. of Administration
Finance Subcommittee
Chairman

Rep.Jason.Grenn@akleg.gov

REPRESENTATIVE JASON GRENN

SPONSOR STATEMENT

House Bill 43

The Right to Try: New Drugs for the Terminally Ill

"Patients should be free to exercise a basic freedom – attempting to preserve one's own life."
- Christina Corieri, Health Care Policy Analyst

House Bill 43 would allow terminally ill patients who have exhausted other available treatments and do not qualify for clinical trials to gain faster access to safe, but experimental drugs in an effort to save their own lives. By providing certain immunities to prescribing physicians, manufacturers and distributors acting in good faith, this bill would allow terminal patients, in consultation with their doctor, the freedom to try new treatments as they fight to survive, without the burden of waiting for federal approval.

More than 1 million Americans die from a terminal illness every year. Many spend years searching for a potential cure, or struggle in vain to get accepted into a clinical trial. Unfortunately, FDA red tape and government regulations can often restrict access to promising new treatments, and sometimes for those who do get access, it is too late.

The United States Food and Drug Administration currently offers an "expanded access" or "compassionate use" exemption that allows terminally ill patients that meet certain criteria to access drugs in the clinical trial phase. However, even with recent efforts by the FDA to streamline the application process, this exemption program is known to be arduous and can take longer than patients facing terminal illness have to wait.

Since 2014, 34 states have signed "right to try" legislation into law with strong, bi-partisan support. It is clear this is a human issue that goes beyond state and party lines, and could provide Alaskans increased access to potentially life-saving treatments in the times they need it most.

In allowing Alaskans facing terminal illness the ability to access safe, though experimental drugs in consultation with a doctor they trust, this bill offers new hope when all FDA-approved options have been exhausted. I urge your support of House Bill 43.

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REPRESENTATIVE JASON GRENN

SECTIONAL ANALYSIS

House Bill 43 ver J

The Right to Try: New Drugs for the Terminally Ill

Section 1: Prohibits disciplinary action of physicians by the State Medical Board for prescribing, dispensing or administering an investigational drug, biological product or device to terminally ill patients that are ineligible or unable to participate in a current clinical trial, have considered all other treatment options approved by the FDA and have provided written consent.

Defines "investigational drugs, biological products and devices" as those that have successfully completed Phase 1 of the FDA drug review process and remain in ongoing Phase 2 or 3 clinical trials or the marketing application process, but have not been approved for general use.

Defines "terminal illness" as a disease that will result in death in the near future or permanent state of unconsciousness from which recovery is unlikely.

Section 2: Establishes immunity for physicians, medical team members, manufacturers and distributors in the case of injury or death of a terminally ill patient from the use of an investigational drug, biological product or device, provided informed consent was obtained from the patient and notice of immunity was given in advance.

Establishes immunity for physicians and manufacturers who choose not to participate in the distribution of an investigational drug, biological product or device.

Section 3: Amends statute limiting the sale and distribution of new drugs (AS 17.20.110) so as not to apply to physicians prescribing or administering investigational drugs under the conditions established in Section 1.

Section 4: Prohibits the Department of Health and Social Services from requiring a licensed health care facility to increase its services solely to accommodate physicians prescribing, dispensing or administering investigational drugs to a patient.

SENATE COMMITTEE REPORT

DATE: 4/11/17

FURTHER: Judiciary

DATE TURNED
IN TO OFFICE: _____

Health and Social Services Committee considered CS FOR HOUSE BILL NO. 43(JUD)

HB 43-NEW DRUGS FOR THE TERMINALLY ILL

"An Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill for the purpose of sustaining the patient's life; providing immunity related to manufacturing, distributing, or providing investigational drugs, biological products, or devices; and relating to licensed health care facility requirements."

and recommends:

- be replaced with SCS _____ (_____) Same Title Technical Title Change
 New Title/SCR No. _____
- adopt previous SCS _____ (_____) Same Title Technical Title Change
 New Title/SCR No. _____
- attached amendment(s)
- adopt _____ Letter of Intent
- further referral to _____ Committee

| Dept Abbr. | |
|------------|-----|
| ADM | LWF |
| CED | LAW |
| COR | LEG |
| EED | MVA |
| DEC | DNR |
| DFG | DPS |
| GOV | REV |
| DHS | DOT |
| AJS | UA |

| NEW FISCAL NOTE(S) | | | | |
|--------------------|--------|--------|------|------|
| Dept. | Fiscal | Indet. | Zero | FN # |
| CED | | | ✓ | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| PREVIOUS FISCAL NOTE(S) | | | | |
|-------------------------|--------|--------|------|------|
| Dept. | Fiscal | Indet. | Zero | FN # |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

APPROPRIATION - no fiscal note

| SIGNATURES AND RECOMMENDATIONS: | PRINTED LAST NAME | DO PASS | DO NOT PASS | NO REC | AMEND |
|---------------------------------|-------------------|---------|-------------|--------|-------|
| | Begich | ✓ | | | |
| | MICCICHE | | | ✓ | |
| | Biessel | ✓ | | | |
| VICE CHAIR | VonImhof | ✓ | | | |
| | | | | | |
| | | | | | |
| CHAIR: | | | | | |

Fiscal Note

State of Alaska
2017 Legislative Session

| | |
|---------------------|----------|
| Bill Version: | HB 43 |
| Fiscal Note Number: | 1 |
| (H) Publish Date: | 3/8/2017 |

Identifier: HB043-DCCED-CBPL-02-24-17
 Title: NEW DRUGS FOR THE TERMINALLY ILL
 Sponsor: GRENN
 Requester: (H) Health and Social Services

Department: Department of Commerce, Community and
Economic Development
 Appropriation: Corporations, Business and Professional
Licensing
 Allocation: Corporations, Business and Professional
Licensing
 OMB Component Number: 2360

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

| | FY2018 | Included in | Out-Year Cost Estimates | | | | |
|-------------------------------|-------------------------|---------------------------|-------------------------|----------------|----------------|----------------|----------------|
| | Appropriation Requested | Governor's FY2018 Request | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 |
| OPERATING EXPENDITURES | FY 2018 | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 |
| Personal Services | | | | | | | |
| Travel | | | | | | | |
| Services | | | | | | | |
| Commodities | | | | | | | |
| Capital Outlay | | | | | | | |
| Grants & Benefits | | | | | | | |
| Miscellaneous | | | | | | | |
| Total Operating | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

Fund Source (Operating Only)

| | | | | | | | |
|--------------|------------|------------|------------|------------|------------|------------|------------|
| None | | | | | | | |
| Total | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

Positions

| | | | | | | | |
|-----------|--|--|--|--|--|--|--|
| Full-time | | | | | | | |
| Part-time | | | | | | | |
| Temporary | | | | | | | |

Change in Revenues

| | | | | | | | |
|--------------|------------|------------|------------|------------|------------|------------|------------|
| None | | | | | | | |
| Total | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

Estimated SUPPLEMENTAL (FY2017) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2018) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
 If yes, by what date are the regulations to be adopted, amended or repealed? N/A

Why this fiscal note differs from previous version:

Not applicable, initial version.

| | | | |
|--------------|---|--------|---------------------|
| Prepared By: | Janey Hovenden, Director | Phone: | (907)465-2538 |
| Division: | Corporations, Business and Professional Licensing | Date: | 02/24/2017 11:00 AM |
| Approved By: | Catherine Reardon, Director | Date: | 02/24/17 |
| Agency: | Division of Administrative Services, DCCED | | |

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2017 LEGISLATIVE SESSION

Analysis

HB 43 prohibits disciplinary action being taken against physicians by the State Medical Board for prescribing, dispensing, or administering an investigational drug, biological product, or device to terminally ill patients that have considered all other treatment options approved by the U.S. Food and Drug Administration and are ineligible or unable to participate in a current clinical trial.

This legislation establishes immunity for physicians, manufacturers, and distributors in the case of injury or death of a terminally ill patient from the use or nonuse of an investigational drug, biological product, or device, provided that informed consent was obtained from the patient and notice of immunity was given in advance.

HB 43 amends the statute limiting the sale and distribution of new drugs so it does not apply to physicians prescribing or administering investigational drugs under the conditions established in Section 1 of the bill. Additionally, this legislation prohibits requiring licensed entities subject to AS 47.32.030 to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment to a patient.

The Division of Corporations, Business and Professional Licensing does not anticipate fiscal impact from this legislation.

Fiscal Note

State of Alaska
2018 Legislative Session

Bill Version: HB 43
Fiscal Note Number: _____
() Publish Date: _____

Identifier: HB043-DCCED-CBPL-01-19-18
Title: NEW DRUGS FOR THE TERMINALLY ILL
Sponsor: GRENN
Requester: (S) Health and Social Services

Department: Department of Commerce, Community and
Economic Development
Appropriation: Corporations, Business and Professional
Licensing
Allocation: Corporations, Business and Professional
Licensing
OMB Component Number: 2360

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

| | FY2019 Appropriation Requested | Included in Governor's FY2019 Request | Out-Year Cost Estimates | | | | | |
|-------------------------------|--------------------------------------|--|-------------------------|------------|------------|------------|------------|------------|
| | | | FY 2019 | FY 2020 | FY 2021 | FY 2022 | FY 2023 | FY 2024 |
| OPERATING EXPENDITURES | | | | | | | | |
| Personal Services | | | | | | | | |
| Travel | | | | | | | | |
| Services | | | | | | | | |
| Commodities | | | | | | | | |
| Capital Outlay | | | | | | | | |
| Grants & Benefits | | | | | | | | |
| Miscellaneous | | | | | | | | |
| Total Operating | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

Fund Source (Operating Only)

| | | | | | | | | |
|--------------|------------|------------|------------|------------|------------|------------|------------|------------|
| None | | | | | | | | |
| Total | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

Positions

| | | | | | | | | |
|-----------|--|--|--|--|--|--|--|--|
| Full-time | | | | | | | | |
| Part-time | | | | | | | | |
| Temporary | | | | | | | | |

Change in Revenues

| | | | | | | | | |
|--------------|------------|------------|------------|------------|------------|------------|------------|------------|
| None | | | | | | | | |
| Total | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

Estimated SUPPLEMENTAL (FY2018) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2019) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed? N/A

Why this fiscal note differs from previous version/comments:

Updated to the 2018 Legislative form.

| | |
|--|----------------------------------|
| Prepared By: <u>Janey McCullough, Director</u> | Phone: <u>(907)465-2538</u> |
| Division: <u>Corporations, Business and Professional Licensing</u> | Date: <u>01/19/2018 01:00 PM</u> |
| Approved By: <u>Catherine Reardon, Director</u> | Date: <u>01/19/18</u> |
| Agency: <u>Division of Administrative Services, DCCED</u> | |

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2018 LEGISLATIVE SESSION

BILL NO. HB 43

Analysis

HB 43 prohibits disciplinary action being taken against physicians by the State Medical Board for prescribing, dispensing, or administering an investigational drug, biological product, or device to terminally ill patients that have considered all other treatment options approved by the U.S. Food and Drug Administration and are ineligible or unable to participate in a current clinical trial.

This legislation establishes immunity for physicians, manufacturers, and distributors in the case of injury or death of a terminally ill patient from the use or nonuse of an investigational drug, biological product, or device, provided that informed consent was obtained from the patient and notice of immunity was given in advance.

HB 43 amends the statute limiting the sale and distribution of new drugs so it does not apply to physicians prescribing or administering investigational drugs under the conditions established in Section 1 of the bill. Additionally, this legislation prohibits requiring licensed entities subject to AS 47.32.030 to increase services for the sole purpose of accommodating a physician's practice of prescribing, dispensing, or administering an investigational drug, biological product, or device, or providing related treatment to a patient.

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REPRESENTATIVE JASON GRENN

EXPLANATION OF CHANGES

House Bill 43

Version D to Version J

1. **Page 1, Line 2 following "ill"**: Inserts "for the purpose of sustaining the patient's life"

Amends the bill title to clarify the use of investigational treatments by terminally ill patients must be for life-sustaining purposes.

2. **Page 1, Line 10 following "patient"**: Inserts "for the purpose of sustaining the patient's life"

Clarifies that prescribing, dispensing or administering investigational drugs to terminally ill patients by a physician must be for life-sustaining purposes.

3. **Page 2, Line 11 following "Phase 3"**: Inserts "or is in the new drug application process following Phase 3 of clinical trials"

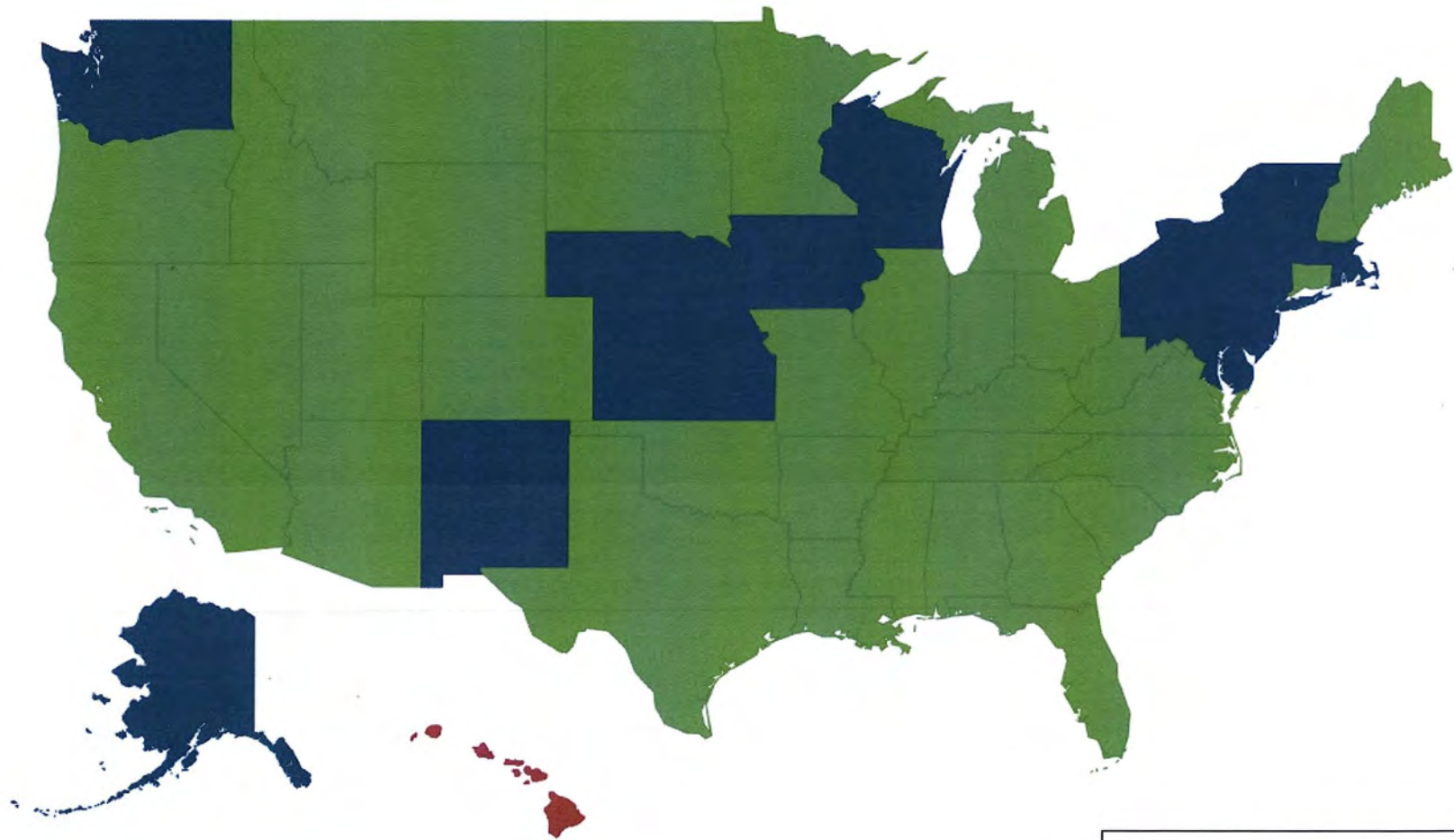
Amends the definition of "investigational drug, biological product, or device" to encompass investigational treatments that have passed Phase 3 of the FDA approval process, but are still not fully approved. This change ensures access to investigational treatments is continuous between Phase 1 and final approval by the FDA, with no gap during the marketing approval phase of the process.

4. **Page 2, Line 21 following "device"**: Inserts "for the purpose of sustaining the patient's life"

Clarifies the use of investigational treatments by terminally ill patients must be for life-sustaining purposes.

“Right to Try” Legislative Map

Updated: April 11, 2017



Green = Signed into Law (34)
Blue = Introduced (15)
Red = Vetoed (1)



The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective

The path a drug travels from a lab to your medicine cabinet is usually long, and every drug takes a unique route. Often, a drug is developed to treat a specific disease. An important use of a drug may also be discovered by accident.

For example, Retrovir (zidovudine, also known as AZT) was first studied as an anti-cancer drug in the 1960s with disappointing results. Twenty years later, researchers discovered the drug could treat AIDS, and Food and Drug Administration approved the drug, manufactured by GlaxoSmithKline, for that purpose in 1987.

Most drugs that undergo preclinical (animal) testing never even make it to human testing and review by the FDA. The drugs that do must undergo the agency's rigorous evaluation process, which scrutinizes everything about the drug—from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured.

Stages of Drug Development and Review



Animals Tested

1

Investigational New Drug Application (IND)—The pharmaceutical industry sometimes seeks advice from the FDA prior to submission of an IND.

Sponsors—companies, research institutions, and other organizations that take responsibility for developing a drug. They must show the FDA results of preclinical testing in laboratory animals and what they propose to do for human testing. At this stage, the FDA decides whether it is reasonably safe for the company to move forward with testing the drug in humans.

Clinical Trials—Drug studies in humans can begin only after an IND is reviewed by the FDA and a local institutional review board (IRB). The board is a panel of scientists and non-scientists in hospitals and research institutions that oversees clinical research.



IND Application

2

IRBs approve the clinical trial protocols, which describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives, and other details. IRBs make sure the study is acceptable, that participants have given

consent and are fully informed of their risks, and that researchers take appropriate steps to protect patients from harm.



3

Phase 1 studies are usually conducted in healthy volunteers. The goal here is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted. The number of subjects typically ranges from 20 to 80.

Phase 1 Testing

Phase 2 studies begin if Phase 1 studies don't reveal unacceptable toxicity. While the emphasis in Phase 1 is on safety, the emphasis in Phase 2 is on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment--usually an inactive substance (placebo), or a different drug. Safety continues to be evaluated, and short-term side effects are studied. Typically, the number of subjects in Phase 2 studies ranges from a few dozen to about 300.



4

Phase 2 Testing



5

At the end of Phase 2, the FDA and sponsors try to come to an agreement on how large-scale studies in Phase 3 should be done. How often the FDA meets with a sponsor varies, but this is one of two most common meeting points prior to submission of a new drug application. The other most common time is pre-NDA--right before a new drug application is submitted.

Phase 3 Testing

Phase 3 studies begin if evidence of effectiveness is shown in Phase 2.

These studies gather more information about safety and effectiveness, studying different populations and different dosages and using the drug in combination with other drugs. The number of subjects usually ranges from several hundred to about 3,000 people.

Postmarket requirement and commitment studies are required of or agreed to by a sponsor, and are conducted after the FDA has approved a product for marketing. The FDA uses postmarket requirement and commitment studies to gather additional information about a product's safety, efficacy, or optimal use.



6

Review Meeting



7

NDA Application

New Drug Application (NDA)--This is the formal step a drug sponsor takes to ask that the FDA consider approving a new drug for marketing in the United States. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.

When an NDA comes in, the FDA has 60 days to decide whether to file it so that it can be reviewed. The FDA can refuse to file an application that is incomplete. For example, some required studies may be missing. In accordance with the Prescription Drug User Fee Act (PDUFA), the FDA's Center for Drug Evaluation and Research (CDER) expects to review and act



8-9

Application Reviewed

on at least 90 percent of NDAs for standard drugs no later than 10 months after the applications are received. The review goal is six months for priority drugs. (See ["The Role of User Fees."](#))

"It's the clinical trials that take so long--usually several years," says Sandra Kweder, M.D., deputy director of the Office of New Drugs in the CDER. "The emphasis on speed for FDA mostly relates to review time and timelines of being able to meet with sponsors during a drug's development," she says.



Facts About “Right To Try”

For terminal patients who have exhausted their conventional treatment options, obtaining access to potentially life-saving investigational medications is often extremely difficult. The patient can attempt to enroll in a clinical trial, but many of the sickest individuals do not qualify. In fact, only 3 percent of cancer patients today are enrolled in clinical trials. For everyone else, their only hope for obtaining potentially life-saving medications is to ask the FDA for special permission.

Only about 1,200 people make it through the FDA’s “compassionate use” application process each year. The process is complicated, time-consuming, and expensive. The first step in the process requires a doctor to complete a complex and time consuming application. After the doctor submits the application to the FDA, the manufacturer must also submit lengthy documentation requirements. The FDA then has a month to review the submission and either grant or deny the request, but if there are any questions the one-month clock starts over. After the FDA approves a request, a separate committee not affiliated with the FDA, called an Institutional Review Board, also must approve the patient’s use of the drug. There is no time limit on when an Institutional Review Board must review and approve or deny an application. Sadly, there are many documented cases of patients dying while their application is being considered.

After a year and half of deliberation, the FDA recently shortened its application form. A shorter application for the first step is helpful, but it only addresses one part of the approval process. And ultimately, it’s still an application to the government to ask permission to try to save your own life. If you have a terminal illness, you don’t have time for a multi-step government process. If your child is dying from a terminal illness and you know there’s an investigational medication that is already helping other children survive, a shorter form isn’t good enough.

We need to remove barriers that limit doctors from providing the care they are trained to give—and this is exactly what Right To Try does.

Right To Try allows terminally ill Americans to try medicines that have passed Phase 1 of the FDA approval process but are not yet on pharmacy shelves. Right To Try expands access to potentially life-saving treatments years before patients would normally be able to access them.

Under Right To Try, a terminal patient would be able to access an investigational medicine if:

- ✓ The patient has a terminal disease and has exhausted all conventional treatment options;
- ✓ The patient's doctor has advised the use of an investigational medication;
- ✓ The medication has successfully completed basic safety testing and is part of the FDA's on-going approval process;
- ✓ The patient has provided "informed consent" acknowledging the potential risk of the drug; and
- ✓ The company developing the medication is willing to make it available to the patient.

Right To Try includes important protections. The basic safety testing and informed consent requirements protect the patient. And doctors and the manufacturer are protected from liability if the investigational medication doesn't work. But this is not protection from medical malpractice.

Right To Try is already law in 33 states: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois, Indiana, Louisiana, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, and Wyoming. It has passed with overwhelming bipartisan support in each state and has been introduced in 16 additional states. Right To Try isn't a red or blue issue; it's a human dignity issue. That's why lawmakers from both sides of the aisle are coming together to protect their citizens' right to try to save their own lives.

The FDA says providing dying people with investigational medications should be an exception. We think it should be the rule. People fighting for their lives should have access to medicines that could save them without needing a permission slip from the government.

For more information about Right To Try visit RightToTry.org. Or contact Starlee Coleman at scoleman@goldwaterinstitute.org or (602) 758-9162.

Right To Try: Patient Stories



Jordan McLinn

Six-year-old Jordan says he wants to grow up to be a firefighter so he can save lives. Jordan has Duchenne muscular dystrophy, which could leave him paralyzed within 5 years and shortens his life expectancy to only 20 years. There is a drug being used in clinical trials now that is helping young children like Jordan. But it could take another seven years for the drug to be available. His parents say they cannot afford to wait for the FDA to give the drug its final approval. He could be in a wheelchair by then. An investigational drug could add years to Jordan's life, which would give him the chance to save others.



Josh Hardy

By the time Josh Hardy was seven years old he had already beat cancer four times. After a bone marrow transplant, he was infected with a rare virus that no drug on the market could effectively treat. But there was a new medicine being made in North Carolina that was having a positive effect in a small clinical trial. But Josh's doctors couldn't get access to it. Aimee, Josh's mom, started telling Josh's story to anyone who would listen. She created a social media campaign that got worldwide attention. Finally, the FDA and the drug company agreed to let Josh have the drug they were already safely giving to others enrolled in the clinical trial. Now, a year later, Josh is home and healthy. It's no exaggeration to say this investigational drug saved his life.



Mikaela Knapp

At 24, Mikaela was diagnosed with a deadly form of kidney cancer that had already migrated into her bones before she even knew she was sick. She went through every known treatment in a matter of months and nothing worked. Mikaela's high school sweetheart, Keith, heard about a drug under development that was successfully treating people with this same cancer. But Mikaela wasn't allowed to enroll in the clinical trial. Mikaela and Keith launched a social media campaign to try to get access to the drug. But it wasn't enough. The FDA didn't help. Mikaela died on April 24, 2014. Five months later, on September 4, the FDA gave final approval to the drug that could have saved her.

Right To Try: Patient Stories



Diego Morris

When 10-year-old Diego woke up with a sore leg, his mom thought “just another sports injury.” When the pain didn’t go away, they knew something was wrong. But they never expected Osteosarcoma, a rare form of bone cancer. After exhausting all treatment options available, Diego’s doctors recommended he try Mifamurtide, which wasn’t available in the United States, but was being safely used and had been given the Prix Galien Award, the gold medal for pharmaceutical research and development, in England. The Morris family wasted no time, and made the move abroad to try to save Diego’s life. The treatments worked and now Diego is home in Phoenix, Ariz. and back to playing his favorite sports. Without access to this drug, currently under approval in the U.S., Diego’s story could have ended very differently.



Bertrand Might

Bertrand is a very special little boy. He was the first person ever to be diagnosed with a rare, fatal genetic disorder called NGLY1 that has left this seven-year-old paralyzed. Because the disease was only identified by scientists in 2012, and only a few people worldwide have been diagnosed with it, there is no cure and no treatment available. Because the disorder is so rare, a drug may not ever be developed to treat it. But, scientists have found that Bertrand responds to certain investigational therapies. So, Bertrand’s family will have to rely on trying new, investigational medications as long as they have access to them.



Ted Harada

Ted was diagnosed with ALS at 38. With no cure, ALS is a certain death sentence—and usually within three years. Ted didn’t want to leave his wife and three young children behind in his early 40s. That was just too soon. Lucky for Ted, he was able to enroll in a clinical trial testing a new ALS treatment. Within weeks of beginning the investigational treatment, something miraculous began to happen. Ted set aside his cane and started to regain his strength. While the ALS didn’t go away, the symptoms began to subside, allowing him to walk 2.5 miles for ALS awareness in a local campaign. Ted is still going strong because of the investigational treatment he is receiving, and now he is fighting for the right of all terminally ill people to take investigational medications.

February 17, 2017

Bob Urata MD
Valley Medical Care
1801 Salmon Creek Lane
Juneau, Alaska 99801

Alaska State Legislature
State Capitol - Room 418
Juneau, Alaska 99801
Fax: 907-465-6597

To Whom It May Concern:

This is a letter of support of for House Bill 43 which would protect physicians and hospitals for treating terminally ill patients with experimental medications that have passed the first stage of approval from the FDA.

I personally have not had to use this, but feel if this was available it would allow me to likely pursue this more as I will know that there is protection from potential lawsuits should something go wrong causing unforeseen patient harm.

I hope you will find this bill favorable for your support. I urge passage by your committee.

Thank you for your service.

Sincerely,

Bob Urata MD
907-723-4144

Dixie A. Hood, LMFT
Juneau, Alaska

February 20, 2017

Alaska State Legislature
State Capitol
Juneau, AK 99801

Subject: House Bill 43 – The Right to Try

Dear Alaska State Legislature,

This letter is in support of House Bill 43, the Right to Try: New Drugs for the Terminally Ill.

For 30 years as a licensed marriage and family therapist, substance abuse counselor and present member of the Juneau Suicide Prevention Coalition, I have provided mental health services and support to many individuals who were suffering from life-threatening diseases, as well as their families. Some were referred to Hospice and Home Care. When help and hope seemed unobtainable, several patients turned to suicide.

I have had HIV clients who were eligible to receive medical marijuana, but moved away from long-time friends and relatives because Alaska state law required administering physicians to be publicly identified. Their doctor believed that was professionally unethical and violated privacy laws. Therefore, they refused to provide marijuana as treatment for their illness. Protection of both patient and physician is critical when the patient's well-being, and even life, are at stake.

HB 43 would enable a patient who has provided "informed consent" acknowledging the potential risk of investigational medication to receive treatment of a drug which has successfully completed Phase 1 of the U.S. Food and Drug Administration's drug review process. It would provide immunity from disciplinary action and liability of doctors and manufacturers who have been willing to make the investigational medication available to the patient.

This would enable a terminal patient the ability to access safe, but experimental drugs when their doctor has exhausted all the FDA-approved options.

This is a humanitarian issue, not a political one. I urge support of House Bill 43.

CC: Representative Jason Grenn

-----Original Message-----

From: E. C. Krome
Sent: Tuesday, February 21, 2017 8:14 PM
To: Rep. Jason Grenn <Rep.Jason.Grenn@akleg.gov>
Subject: HB 43

I have been a registered nurse since 1979. I fully support this bill and am incredibly thankful to you for introducing it. It is terrible to take hope away from those with a terminal illness.

E. C. Krome
3642 N. Sams Dr.
Wasilla, AK. 99654

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This e-mail was sent from a contact form on Representative JASON GRENN's legislative website (<http://akhouse.org/rep-grenn>)



THE STATE
of ALASKA
GOVERNOR BILL WALKER

Department of Commerce, Community,
and Economic Development

STATE MEDICAL BOARD

550 West 7th Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8163
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February 24, 2017

The Honorable Bill Wielechowski
State Senate
Alaska State Capitol
Juneau, Alaska 99801

The Honorable Jason Grenn
State House of Representatives
Alaska State Capitol
Juneau, Alaska 99801

Senator Wielechowski and Representative Grenn:

The Alaska State Medical Board has reviewed Senate Bill (SB) 19 and House Bill (HB) 43, which propose to provide immunity for, and prohibit disciplinary action of, physicians for prescribing, dispensing, or administering an experimental drug to terminally ill patients that have considered all other treatment options approved by the FDA and is ineligible or unable to participate in a current clinical trial.

During the previous legislative session, the Board had opposed similar bills; however, the previous position is not relevant to the current bills, as they are different. The Board noted that the previous bills allowed for use of drugs that may be in Phase 1 of testing, and the current bills are for drugs in Phases 2 or 3. The Board also noted that the two current bills are nearly identical, except that HB 43 includes provisions for the both use or non-use of these drugs.

The Board determined to take a neutral position on SB 19 because it does not include the "non-use" clause; the Board supports HB 43 as written.

Sincerely,

Grant Roderer, M.D.
Board President
Alaska State Medical Board

E-mail: medicalboard@alaska.gov

Website: <https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/StateMedicalBoard.aspx>



P.O. Box 13458
Los Angeles, CA 90013
213.935.0553

Feb. 24, 2017
Re: Support for HB43

Dear members of the Alaska legislature,

The Tenth Amendment Center fully supports passage of HB43 enacting a "Right to Try" law in Alaska.

Sometimes the wheels of bureaucracy move slowly. For most of us, this merely presents an inconvenience, but for a patient suffering from a life-threatening illness, a few months could mean the difference between life and death.

The FDA approval process is meant to protect the public and ensure only safe and effective treatments find their way into the marketplace. But sometimes the nature of the process means delays in getting medicines into the hands of those who desperately need them. "Right to Try" laws create a bridge spanning a gap between federal regulations and the needs of terminally ill patients.

We've seen firsthand what "Right to Try" means for more than 70 cancer patients in Texas. Treatment ended after the FDA declined to extend a clinical trial.

"Essentially, my job was to go back to these patients and family members, and tell them that, 'Sorry, I mean the FDA has told me not to continue in this treatment,'" Dr. Delpassand said.

But when the Texas Right to Try bill went into effect, he was able to resume treating his patients under the new state law.

"I can tell you that when I was talking to our patients, when I told them about the news, they were just so happy to hear this. This was such good news for them and gave them such a great hope to understand and know they can get their treatment."

This type of legislation illustrates the beauty of federalism. People have recognized a glaring need and met it through legitimate state action.

So far, 33 states have enacted "Right to Try," and several states will likely be added to the list this year.

We strongly urge you to vote yes on HB43.

Sincerely,

Michael Boldin, Tenth Amendment Center Founder and Executive Director
Mike Maharrey, Tenth Amendment Center National Communications Director

-----Original Message-----

Sent: Monday, February 27, 2017 2:12 PM

Subject: Written Testimony in support of HB43 New Drugs for the Terminally Ill

Representatives Drummond, Gara, Grenn, and Kawasaki (Sponsors of HB43):

I write to you today in support of HB43 with the short title "New Drugs for the Terminally Ill". I understand that your time is limited and therefore I will effort to be as brief as possible. In June of 2011, my father was diagnosed with Amyotrophic Lateral Sclerosis (ALS), sometimes known as "Lou Gehrig's Disease". For those unfamiliar, this disease slowly saps a person's ability to move, rendering them bedridden. Eventually, it takes away their ability to breathe, at which point, they die. It should be noted that the disease does not affect a person's mind. Therefore, they are acutely aware of their daily deterioration and because of this, the mind becomes a prisoner within the body. For my father, the deterioration began in June with a reduced range of movement in his left leg. At this point he had been working 12-hour days 5-6 days per week as a machinist. I feel this is important to point out because of the extended hours and physical nature of the job. He was by all accounts a very strong and healthy man at the time of diagnosis. By late fall, he had completely lost the ability to walk. At Thanksgiving, he held our then 5-month old son for the last time as his arms had become too weak for him to trust with such precious cargo. When he finally lost all movement in his limbs, he would "hug" our children by nuzzling his face against them.

As we entered the depths of winter, he and I carried on what conversations we could, trying to accelerate what should have been many more years of passing knowledge and wisdom from Father to son. These conversations became increasing difficult as the disease made his breathing quite labored, even with the assistance of a [bipap machine](#). While the painful and emotional moments are too many to list, the most painful came when I asked him the simple question, "Dad, are you angry?" He responded with uncommon grace and humility by uttering one word with every labored breath. "I'm. Not. Angry. I'm. Just. Sad. That. I. Won't. See. Your. Kids. Grow. Up." In the early morning hours of February 1, 2012, he died at the all-too-young [age of 58](#).

My father was a good man and my hero. He was a tireless worker, a great role model, and an unparalleled family man. He took a chance on Alaska in 1996 when he moved his family from the only home it had ever known to a place where we had no connections, no network, no family, and no friends. The gamble paid off for all of us. He saw the potential in this place. He fought like we all do to make a life here. In the end, I wish the State had afforded him the right to fight his disease with the same ferocity. Recently, in the Washington Post, there [was an article](#) detailing the experience of a man who has for all intents and purposes beaten ALS through advanced therapies pioneered by doctors at the Emory ALS Center in Atlanta, Georgia. In reading about this man, I became aware of the "Right To Try" movement. Soon thereafter I became aware of the bill which I write to you in support of today. I implore you to pass this bill and to encourage your colleagues in the Senate to do the same. I cannot say for sure that these advanced therapies would have saved my father's life, but they may yet save someone's father or mother, daughter or son.

Thank you all for your consideration of this important legislation. If you have any questions, feel free to contact me via this email address or at the information below.

Jason Norris
12026 Tidepool Place
Anchorage, Alaska
99515

CC: House Speaker Rep. Edgmon, House Majority Leader Rep. Tuck, House Minority Leader Rep. Millett, Rep. Kopp (House District 24), and Sen. Von Imhof (Senate District L)



THE STATE
of **ALASKA**
GOVERNOR BILL WALKER

Department of
Health and Social Services

ALASKA COMMISSION ON AGING

P.O. Box 110693
Juneau, Alaska 99811-0693
Main: 907.465.3250
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February 28, 2017

Representative Jason Grenn
Alaska State Capitol, Room 418
Juneau, AK 99801-1182

Subject: Support for HB 43, New Drugs for the Terminally Ill

Dear Representative Grenn:

The Alaska Commission on Aging (ACoA) is pleased to offer our support for HB 43, a bill authored by you and co-sponsored by Representatives Scott Kawasaki, Les Gara, and Harriet Drummond, that would allow terminally ill patients who have exhausted other available treatments the "right to try" investigational treatments after consultation with their doctors and to provide immunity to their prescribing physicians, manufacturers and distributors of new treatments that have not yet received federal approval.

End of life care is particularly important to older Alaskans and their families. In addition to the potential lifesaving measures that experimental drugs may offer, new treatments can also reduce the pain, discomfort, and inflammation that often accompany terminal illnesses and provide another option to use instead of narcotic drugs. Although the Food and Drug Administration has a process called "compassionate use" that provides patients with terminal illness access to unapproved treatments still in clinical trials, we understand that this process is onerous and can take considerable time to pursue, which is a luxury that a person at the end of life simply cannot afford.

Decisions regarding medical care are personal and belong to patients in consultation with their doctors. If a patient is willing to try a new treatment and understands the risk, and the doctor believes that the treatment may help the patient more than anything else that is available, then the patient with limited and precious time should have the final say in their treatment. Further, patients also have the right to know that these treatments are costly and typically not covered by private insurance and public funding. Ultimately, payment for an investigational treatment will depend on the agreement reached by the patient, his/her doctor, and the drug manufacturer. To this end, we recommend language to be included in the bill that would require medical practitioners to counsel their patients about costs and payment responsibility for unapproved treatments in order to promote transparency and reduce disappointment.

The Commission supports HB 43 and appreciates your leadership of this legislation. We believe that HB 43 will provide hope to Alaskans who suffer from a terminal illness by offering access to investigative treatment options and creating new research pathways to save lives. Please feel free to include the Commission's letter in the bill packet for HB 43.

Sincerely,

Handwritten signature of David A. Blacketer in blue ink.

David A. Blacketer
Chair, Alaska Commission on Aging

Sincerely,

Handwritten signature of Denise Daniello in blue ink.

Denise Daniello
ACoA Executive Director

Cc: Representative Scott Kawasaki
Representative Les Gara

Representative Harriet Drummond



Eugene Huang, M.D.

1701 Salmon Creek Lane

Juneau, AK 99801

Phone: 907.586.5762

3/1/2017

To Whom It May Concern,

I am writing this letter in support for House Bill 43, "New Drugs for the Terminally Ill." I believe that this bill will help provide terminally ill patients greater access to the new drugs that may potentially make a significant difference in their lives.

Sometimes in our practice, a patient may be in a situation where they have exhausted all available options, yet have not given up hope and want to try additional measures that may help them. Every other week, even just within my limited scope of cancer practice, there are new drugs being developed and tested in early-phase clinical trials. The pace of biotechnology research and drug development has significantly accelerated in just the last few years, offering patients more options and hope for treatment.

I believe that House Bill 43 will help bring new scientific discoveries closer to patients whom need them, within the appropriate context and safeguards.

Sincerely,

A handwritten signature in blue ink, appearing to read "E. Huang", is written over a light blue horizontal line.

Eugene H. Huang, MD

Medical Director

Southeast Radiation Oncology Center

Clinical Trials

A student's interviews of nurses, patients and survivors experience and opinions of cancer and cancer clinical trials in Alaska.



Written by: Jennifer Kiser MSW | Edited by: Amanda McDade
& individual interviews final edited by Interviewee.

Introduction

Clinical Trials in Alaska

This booklet combines a student's interviews of nurses, patients and survivors experience and opinions of cancer and cancer clinical trials in Alaska.

A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments.

Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective.

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Krista Rangitsch

Research Nurse, Providence Cancer Center



Krista Rangitsch, a research nurse at Providence Cancer Center, works closely with doctors and their patients by providing them with information on clinical trials. She explains that “cancer clinical trials are research studies involving human subjects that look at ways of preventing, detecting, and/or treating cancer in the hopes of improving overall survival and patient quality of life. These trials help doctors find better ways of improving cancer care by answering certain

“Clinical Trials ... look at ways of preventing, detecting, and/or treating cancer.”

scientific questions.”

She also explained “There are a variety of different ways cancer clinical trials are designed.

Some trials look at new experimental treatments for cancer, while others look at treatments that are already approved by the United States Food and Drug Administration (FDA) for one type of cancer but are being studied in another type of cancer. Alternatively, clinical trials can compare the difference between two or more treatment regimens (i.e. medication “A” compared to medication “B”). Some trials investigate administering an FDA approved medication on a different schedule (i.e. once a week versus every three weeks) or in a different manner (i.e. oral versus intravenous).”

When discussing with a patient potentially interested in participating in a cancer clinical trial, Rangitsch informs them of the risks and benefits of participating and that their insurance may not cover some or all of the care associated with the clinical trial. Acting as an intermediary for the patient, Rangitsch will often contact their insurance provider to request coverage for the routine care costs associated with the clinical trial. Generally the items considered to be investigational are provided at no charge to the participants or their insurance company.

“These trials help doctors find better ways of improving cancer care by answering certain scientific questions”

Some insurance companies have been more difficult to work with than others. One company in particular refused to pay for routine care costs of a patient considering participating in a clinical trial for

Clinical Trials

her soft tissue sarcoma. Rangitsch stated that the sponsor of the study was willing to “pay for everything outside the standard of care”; meaning that all extra costs would be paid for. The only thing the insurance company was being asked to cover were the routine care costs associated with standard sarcoma care follow-up, which they would have incurred even if the patient was not enrolled in the clinical trial. The patient was very frustrated, saying that she has worked her entire life paying for health insurance coverage and expected that it would be there when she need it. Now, because they will not pay for routine care costs during this clinical trial she is actually considering paying for her treatment out of pocket.

Other insurance companies have made things very easy. Rangitsch mentioned that working with one company in particular has been a great experience; they cover the routine care cost during a clinical trial and the process for approval is clear and simple. Rangitsch has testified as a private citizen in support of Senate Bill 10 which would mandate that insurance companies in Alaska cover the routine care costs associated with a clinical trial. Creating equal access to clinical trials is “so important because it is currently a huge barrier. Clinical trials are how we improve and advance medicine, and clinical trials are the only way to get new drugs approved.”

*“Clinical trials
are the only way
to get new drugs
approved”*

Kathy

Clinical Trials Story



Kathy found a lump in her breast but was not alarmed by it, it just seemed kind of weird that there were little red dots on the outside of the breast and there was something on the inside that was a little bit hard. She thought that cancer was large, defined, marble size lumps, not something like this, so she thought it just might go away and went back to her busy life taking care of her children and supporting her husband. Kathy stated “I wasn’t thinking about myself,” too much seemed to be going on for her to worry about something that didn’t seem like cancer.

Several months later she noticed the lump was still there, and her body started to get progressively weaker. She tried to make an appointment at the local Breast Cancer Detection Center for a mammogram, but was told she needed a prescription. Her insurance company insisted that she go to the urgent care clinic for doctor visits, so she decided to go there hoping they could give her a prescription. Still not too alarmed, because throughout her life she had taken precautions to reduce the risk of cancer, Kathy was checked by an urgent care doctor. Because the urgent care center doctor wouldn’t give her a prescription for a mammogram, the Dr., with urgency in her voice, made an appointment for Kathy to be seen by a gynecologist - that hour! It was then that she experienced fear for the first time. She drove straight to the gynecologist’s office, and was examined. He stated that he would call and order a mammogram and ultrasound, and that she should make the appointment as soon as possible. She went home a little shook up, and thought about how scared she was over the possibility that she might have breast cancer. Finally, after several days, she got enough nerve to call and make an appointment. However, the next available appointment was three weeks out, which gave her even more time to be frightened.

“I wasn’t thinking about myself,” too much seemed to be going on for her to worry about something that didn’t seem like cancer.

During the mammogram, the radiologist just kept taking pictures. As he looked at the ultrasound he said he thought the mammogram looked “suspicious.” Kathy said “I felt sick to my stomach.” Not wanting to delay anything further, the radiologist set up an appointment for a biopsy later that week. Since they

Clinical Trials

were already booked solid, he set it for a time that was outside the normal “biopsy schedule.” It was for 7 AM — a time that would be most inconvenient for her, because she had four kids at home to get ready for school. Unable to bare the thought of explaining to her kids why she had to leave so early in the morning, she got up in the middle of the night and left while everyone was sleeping. She left notes for her husband and kids telling them she had gone to her friend’s house. Unbeknown to anyone, her friend was going to accompany her to the appointment. The next morning, the gynecologist called her while she was at school with her youngest daughter; he told Kathy it was a malignant tumor.

“I felt sick to my stomach.”

According to Kathy, she got up, kissed her six year old daughter, and told her she’d still be at the school, but would be outside. She went to her car, and cried. After a while, she called her mother, her husband, and two of her friends. One of them came up to the school and sat with her in the parking lot — they both cried.

“Not knowing what her future held, she wondered if this would be the last time she’d ever see her kids poking their heads out the bus window, waving goodbye for the summer.”

She knew she had to collect herself because in just a little while school would be out, and not just for the day; it was the last day of school before summer, and there were year end traditions to uphold.

Things weren’t going to change just because she had breast cancer. At her kids’ elementary school, on the last day of school, once the kids

board the buses for home, they do a bus parade and circle the parking lot several times. The entire school staff comes outside and waves goodbye to the kids. With four kids, this was a tradition she hadn’t missed in ten years. She tried to pretend things were perfectly normal but did not do very well. Instead, she felt very emotional.

Not knowing what her future held, she wondered if this would be the last time she’d ever see her kids poking their heads out the bus window, waving goodbye for the summer. Her other daughter’s teacher noticed she was teary eyed. Unable to speak at first, she finally got the words out – she was “just diagnosed with breast cancer three hours ago.” As difficult as it was for her, she was trying to hide her emotions. She surely didn’t want her two youngest daughters seeing her cry. She remembers him putting his arm around her, trying, in his most reassuring tone,

“Kathy wanted to do something... she found a press release on the Zometa clinical trial and showed it to her doctor.”

to tell her that she would be okay. The most difficult part for Kathy was the fear of what would happen to her kids if she died.

After visiting the surgeon she felt hopeful because the tumor was less than two centimeters. Things were looking better, and the surgeon was very encouraging. After more than a week of not being able to eat, or even drink water, she was finally able to eat, and enjoyed a plate of fettuccine, which is her favorite food. She had already lost more than five pounds by then. Kathy remembered thinking how she wanted to go on a diet that summer, but the cancer diet was never in the plan.

Kathy wanted to do something. Shortly after her diagnosis, she heard about the drug Zometa. Manufacturer's had been working with Zometa, and found that the drug that has shown positive correlations with fewer reoccurrences of breast cancer. At the time, her Dr. told her Zometa was normally used to treat bone cancer, and they had not heard of it being used to treat breast cancer. A couple of weeks later, at the ASCO Conference in Chicago, it was announced that Zometa had shown promise in a limited clinical trial. Kathy found a press release on the Zometa clinical trial and showed it to her doctor. Her internet research quoted one doctor to say that Zometa will "probably become the standard of care."

It took a lot of thought to make sure it was something she would want to do and wondered if it would be beneficial.

After several months into chemotherapy, Doctor Cox mentioned the Zometa study was expanding and she would be a likely candidate. She advised her to read about the clinical trial to see if it was something she really wanted to pursue. This trial was a much more aggressive treatment than what she had heard about in the previous study. It took a lot of thought to make sure it was something she would want to do and wondered if it would be beneficial. Her initial reasons for participating in the clinical trial were so that she would receive additional treatment. It seemed as though the additional drug would be beneficial. After careful consideration, Kathy decided to enroll in the clinical trial. She was hoping to be randomized to the Zometa arm of the study. Instead, she was selected to take Clodronate, which is not approved in the United States. The three drugs within the study are all in the same drug family and, to her knowledge Clodronate has only been used in the UK, Canada, and Italy. This led her to weigh her options to see if she wanted to drop out or remain in the study. Kathy knew remaining in the study was optional. She began to research Clodronate but she could not find much information about it. What she did find she was conflicting, and there were not any significant end result findings from using this drug. The study is looking at its effectiveness in the reoccurrence of cancer as compared to the other two drugs, Zometa being one of them. Kathy said "I will just go ahead and do it. There are thousands and thousands of women before me that

Kathy — Clinical Trials Story

this was not even offered to, and it has promise. I am fortunate to have this option. A year ago, I would not have had the option to be on this drug.” She now has follow-up care scans which would have not been done otherwise. According to Kathy “people are going to monitor me for a long time.” In Kathy’s case, the standard of care was going to be less than what she will get from the clinical trial.

It was not easy to get on this study. Kathy encountered several challenges when dealing with her insurance company even though she pays \$900 dollars a month for health insurance coverage. They denied her requests to participate in the study three times. That was no surprise to her - they denied more than half the cost of her surgery too, possibly due to doing a double mastectomy,

“There are thousands and thousands of women before me that this was not even offered to, and it has promise. I am fortunate to have this option. A year ago, I would not have had the option to be on this drug.”

rather than the suggested lumpectomy or single mastectomy. Kathy researched her cancer type and felt there was a high chance of the cancer occurring in both breasts, so she opted for the double mastectomy to reduce her risk of reoccurrence. In Kathy’s clinical trial, only the drug is paid for by the manufacturer, the follow up care is not. Without approval, remaining on the study would not be an option for her because she could not afford it on her own. Finally, with only three days to spare in the 8 week window, they agreed to cover the costs associated with it.

Kathy continues to fight her breast cancer, and is learning to live with the diagnosis. As the interview ended, she stated “Where ever you go, there you are” because she can’t get away from herself. Her diagnosis will follow her wherever she goes. She left me with a quote that she often tells her daughters “The sky is always blue above the clouds. Its always sunny somewhere.” This left me with an understanding that Kathy is a fighter, looking for a silver lining in a sky full of gray.



Without approval,

“The sky is always blue above the clouds. Its always sunny somewhere.”

Claire

Clinical Trials Story



Claire's sister had breast cancer eight years ago. When Claire found out she too had breast cancer, it was shocking but not surprising. It was found during a mammogram and after three scans, the doctors found the cancerous cells. Claire ended up having a mastectomy which found a small node of cancer. Doctors recommended that she also undergo radiation and chemotherapy but Claire chose not to do either. According to Claire it took a lot of research and studying statistics to figure out her chances of survival.

It took a lot of research and studying statistics to figure out her chances of survival.

In 2006, Claire had the opportunity to be enrolled in a clinical trial for bone strengthening, and she thought it would be beneficial. The trial had several different groups which would be receiving different forms of treatment. Claire would be randomly assigned to a group, but because of her fear of needles, she projected which group she would be in. Just as she had guessed, she was assigned to be in the only group that required an IV. At first, Claire was going to the hospital quite often to have treatments done. As time progressed, she had the IV treatments less often and did not require as many hospital visits. She has had no side effects from the IV treatments unlike the other groups who received different drugs.

Not only did Claire receive numerous personal benefits from the clinical trial, she also helped advance research.

Because Claire chose to take part in the clinical trial she will receive lab tests and doctors visits to monitor the effectiveness of the treatment for years to come. Claire is convinced that this clinical trial will help her bone strength and decrease the probability of bone cancer.

Even though there were several positive aspects to the clinical trial, Claire did encounter one problem. During the clinical trial the insurance company would only cover a part of routine care cost during the clinical trial even though some of the treatment options on the clinical trial were well established and widely prescribed in other countries. When Claire's sister went through treatment, she was living in Britain and did not encounter any problems when participating in research. She received fabulous care with universal health coverage.

Claire — Clinical Trials Story

Not only did Claire receive numerous personal benefits from the clinical trial, she also helped advance research. Claire thinks of herself as a statistic that could be measured and studied through her clinical trial journey. It is important to have these statistics and patients associated with new treatment options in order to give the treatment more credibility and help it become well-established. As Claire stated, “How do we find out about new drugs or treatments if we do not conduct clinical trials?”

“How do we find out about new drugs or treatments if we do not conduct clinical trials?”

Connie

Clinical Trials Story



In early 1999, there was a lump on the side of Connie's neck. The lump did not come with a cold or any sickness, so she let it go. Three months later the lump had not gone, yet there was still no pain, illness or anything substantial that would cause her to worry. As a precautionary measure she went to her doctor and received blood work.

In April 1999, Connie was diagnosed with Non-Hodgkin's Lymphoma, a cancer that affects the immune system and the bodies'

Non-Hodgkin's Lymphoma, a cancer that affects the immune system and the bodies' ability to fight infection.

ability to fight infection. She learned that this type of cancer is less aggressive than Hodgkin's Lymphoma; however, there is also no cure.

Through the use of her computer and her husband by her side, Connie learned as much as she could about the Non-Hodgkin's' Lymphoma which helped ease some fears. She found that this type of cancer is slow growing which gave her time to look at various treatment options and how the disease progressed in the body.

By looking at treatment options for this type of diagnosis, Connie learned that it would be treated with chemotherapy. As Connie continued to learn about her disease she discovered a clinical trial her doctor had mentioned from the National Cancer Institute. She would be able to advance medical treatment through this clinical trial. The vaccine study would take a sample of one of Connie's nodes and mix it with another enzyme to try to create a vaccine which would attack her specific cancer. According to Connie the study "gave me hope for a possible cure," and although the study was a double blind study, she would be able to take part in possible advances in cancer research. In this study Connie will be followed for the next ten years which is much longer than a person who just receives standard treatment.

Clinical trials "gave me hope for a possible cure."

Statistically 30 to 40 percent of those with Non-Hodgkin's Lymphoma convert to a more aggressive type. Connie's did while on vacation in New Zealand in 2004. She began to have severe stomach pains and flew to Australia for a scan. The scan showed that her belly was full of cancer. Connie chose to come back to Alaska for treatment. At this point the cancer had blocked

the blood flow to the legs which caused a clot. The clot then traveled to her pulmonary artery which caused a pulmonary embolism, leaving her weak, short of breath and her body atrophied. The doctors suggested that she begin chemotherapy. After treatment she felt much better however the doctor suggested a stem cell transplant which sifts old and new cells, and stores the new cells. She received a high level of chemotherapy treatment with the hope of killing off all cancer affected cells in her body & essentially destroying her immune system. Then, they reintroduce the saved stem cells which were also treated with chemotherapy and put back into her body with the hope of introducing a healthy immune system. About this time she was offered a second clinical trial. The new trial involved a medication that would help to stimulate the mucus membrane cells in the mouth. This trial would help those who receive chemo have less pain and sores in the mouth. In Connie's case, the drug helped reduce the number of days with sores by a day or two.

Connie also participated in a third clinical trial which was very different from the first two. The researchers conducted a psychological study to gauge feelings about the stem cell treatment before and after the treatment. It gave her the opportunity to find how her feelings have changed over time. The study also gave researchers insight on mood and attitude during and after treatment.

***Clinical trials
“made me feel like
I was advancing
medical treatment
and patient care.”***

Connie feels supported by her family, friends and doctors. She stated the clinical trials “made me feel like I was advancing medical treatment and patient care.” She is encouraged by clinical trials and feels like there are not nearly enough people in them. After all, no cancer advancement can occur without participation in clinical trials. Connie also feels that each person has to choose for themselves if they want to participate, weighing the benefits and risks of the trial.

***Connie chose to come
back to Alaska for
treatment.***

***A third
Clinical trial...***

Throughout the three clinical trials Connie was worried about insurance covering the costs. But the National Institute of Health paid for all of the clinical trials and gave her a partial stipend for travel, room, and board. All of her clinical trials had to be preapproved by the insurance company and she worries that the insurance she has will soon run out because the cost of treatment is so expensive.

***Each person has to
choose for themselves
if they want to
participate, weighing
the benefits and risks
of the trial.***

Dennis

Clinical Trials Story



Late summer early fall of 2007, Dennis started to notice a change. It was prostate cancer, not that he knew it at the time. He had problems urinating and a sore left shoulder. The year also involved a broken ankle, which took several months to heal, and continual shoulder pain. By early April of 2008 Dennis became very ill. His roommate was very concerned and convinced him to see a doctor. After the appointment was set up, Dennis began to feel better so he thought about just skipping it because going to the doctor seemed like overreacting. Though he was feeling better,

he kept his appointment. The doctor gave him several blood draws and he waited to hear the results from the doctor's office.

Dennis stated "On April 9th 2008 I was told I had kidney failure." He was directed by his primary care physician, Dr. Reeves, to report immediately to the hospital emergency room. Dennis went through a series of tests and was then admitted to Providence Hospital where he remained for one week. Further testing revealed that prostate cancer was blocking the urinal tubes. Short term treatment for the kidneys was dialysis for several days a week for up to a year. Stents were placed to drain the kidneys and they were so effective that his dialysis treatment was rescinded.

Dennis stated "I had Stage 4 prostate cancer; Dr. Ferucci, my urologist, explained that normal PSA (Prostate Specific Antigen) levels range from .1 to 4, and my PSA level was well over 400." Dennis was

"I had Stage 4 prostate cancer."

Dennis was ready to fight prostate cancer.

ready to fight prostate cancer. Dr. Ferucci suggested hormone treatment which is the standard treatment for those with stage 4 prostate cancer. This treatment halts testosterone and attempts to prevent the cancer from growing. A group of medical professionals, including a urologist, oncologist and hospital staff teamed up to help Dennis fight his cancer. They began hormone treatment which consisted of monthly injections of Lupron along with an oral medication called Casodex which is consumed once a day. In addition, they began radiation

treatment in both shoulders and the left and right femur areas to reduce the heavier concentration of the cancer which had spread to other parts of his body. The hormone treatment was very effective and within 30 days Dennis' PSA level

Dennis — Clinical Trials Story

dropped to around 20. Within another 60 days his PSA level was below 4.

Dr. Ferucci introduced Dennis to Krista a research nurse who knew of a clinical trial for prostate cancer taking place in Alaska. Dennis jumped on board “not in an effort to get better, but to participate in research. Prostate cancer research is ten years behind that of breast cancer, and men are less likely to participate in clinical trials.” The clinical trial utilized a new type of drug substituting Lupron to Zoladex. The use of Zoladex was monitored through blood draws. After PSA levels began increasing it was decided by Dennis and his doctor that removal from the study was the best option.

During this clinical trial, Dennis incurred very little out of pocket expenses because his insurance company was very supportive by covering the cost of his routine care during the clinical trial.

After the clinical trial, Dennis’ medications were returned to current treatment options. He plans to bring his team back together to look at treatment options for cancer in his femurs, along with trying a new diet plan for a more natural treatment option.

Though Dennis has gone through a very difficult time his presence is felt when he walks into a room. He has personal strength and support from his friends. Through this difficult time Dennis is encouraged that research will help future generations find better options to cancer treatment.

Prostate cancer research is ten years behind that of breast cancer, and men are less likely to participate in clinical trials.”

Hannah

Clinical Trials Story



Brice Smith, a cancer research nurse, screens people to determine whether or not they are eligible for clinical trials. She educates staff and patients on what clinical trials are. When patients are enrolled in a clinical trial she is the liaison and case manager during the trial.

During one experience in attempting to enroll a patient in a clinical trial the patients' physicians' office staff and the data center staff, both called the insurer to attain coverage and both were declined three separate times. The data center staff contacted

Hannah regarding the insurance companies' decline of coverage for the patient during the clinical trial. When Hannah contacted the insurer they referred her to the case management group where she spoke with a lead case manager who would review the patient's file. The lead case manager stated the insurance company was "emphatic" that no payment for treatment would be provided while the patient was participating in clinical trials and none of the clinical trial would be paid for. Hannah then asked the lead case manager for something with the insurance companies' logo on it stating the reasons the client was declined, because the Clinical Trials Workgroup is gathering documentation for legislation. The lead case manager from the insurance company called back three days later stating the company needed more information in the form of a letter on some of the benefits of the clinical trials for example: while in the clinical trial all medications will be paid for. After sending in the letter identifying the benefits of the clinical trial an approval was granted within 48 hours.

Attaining coverage for this one patient was five weeks of work; the amount of money spent in time to get the coverage would have cut the cost of insurance company's time and the cost of time for hospital staff.

Hannah pointed out that NCI released a statement that the best care a patient can receive is when enrolled in clinical trials. Under the scrutiny of clinical trials patients are monitored more closely. This particular patient will receive ten years of follow up care. By participating in a clinical trial, this person is on the radar when they would not normally be on the radar.

The best care a patient can receive is when enrolled in clinical trials.

Judy

Clinical Trials Story



For over fifteen years doctors have told Judy that she had a fibroid in her pelvis. In the summer of 2006 it started to interfere with the flow of her urine, the kidney was not draining properly. It was probably never a fibroid, she was diagnosed with Leiomyosarcoma. It was probably a low grade cancer but somehow it had kicked up into high gear and spread. The cancer Judy has is very rare and there is not much research on it, she states “the research needs to get done.”

“The research needs to get done.”

During a hysterectomy the doctors did not do anything to the tumor but they urged her to go to a cancer center and get an appointment with an oncologist. She stated “it was difficult to get an appointment” and after contacting several hospitals she decided to go to Memorial Sloan Kettering Cancer Center. So Judy went to New York and was seen by a surgical oncologist who told her she needed to shrink the tumor before they removed it. She flew back to Alaska and had four rounds of chemotherapy, she went back and forth from Alaska to New York before the surgical oncologist and urologist at Sloan Memorial felt that they should go forward with surgery because the cancer was not diminishing in size.

According to Judy, Memorial Sloan did an incredible job. She returned home receiving cat scans every four months in Alaska and once a year in New York. In January of 2008 Judy learned that the tumor had returned, two more nodes were present in her right lung, she was able to have the two nodes removed. She was sent home for radiation with surgery on the primary pelvic tumor scheduled for the end of May. Returning in May, the surgeon decided removal was unsafe, she was sent back to Alaska for more chemotherapy. During this trip she was able to stay at a place called Hope Lodge sponsored by the American Cancer Society which provided free housing during her treatment in New York. When back in Alaska Judy received chemotherapy, the doctors stated if it stabilized there was an oral drug she could take; she just had to finish the fourth round of her chemotherapy. During the fourth round, the cancer grew and spread.

With all treatment options exhausted Judy is only left with clinical trials.

Now with all treatment options exhausted Judy is only left with clinical

Judy — Clinical Trials Story

trials, however the insurance company is not willing to pay for routine care costs during the clinical trial. They refuse to help with the cost even though the doctors are recommending them as a best option because all other treatments have failed. The health board for her insurance company will look at supporting clinical trials in April of 2009. If the health care plan still refuses coverage, she will have to pay out of pocket. Her next step is to have a metal plate put into her right femur from hip to knee, because of a tumor, doctors are worried it could break without this support. Judy is waiting to continue the clinical trial until after this treatment and radiation.

Judy mentions the importance of having a support network, and feels even if the clinical trial doesn't do anything for her at least we learn something. She stated "I would hate to think that this was all (the cancer) just a waste" in the mean time "I have worked, played, and seen my grandson."

A team approach to health care is needed because it's a lot of work managing your own health care when you have cancer with oncologist, urologist, doctors, radiologist, and nurses at various places across the country. Judy continues to fight her battle with cancer; her strength is seen in her courage to continue to fight, even though getting around is sometimes a battle.

"I would hate to think that this was all (the cancer) just a waste."

Myths and Facts

About Cancer Clinical Trials

Myth: Cancer patients avoid clinical trials because they are too risky.

Fact: Many patients simply don't know that clinical trials are a treatment option. In one survey*, most of these patients said they would have enrolled if they had known. In clinical trials, patients are watched closely by their doctor. They are also watched by other members of their medical team.

Myth: Patients in clinical trials are treated like “guinea pigs.”

Fact: 97 percent of people in one survey* said they were treated with dignity and respect. They also said that the care was very good.

Myth: Cancer clinical trial patients are given “sugar pills.”

Fact: Patients who join clinical trials are given the best treatment available or the chance to receive a new treatment being considered.

Myth: Medicare does not cover the patient care costs of clinical trials.

Fact: Medicare has been covering these costs since June of 2000.

Myth

You need to be near a big hospital to take part in a clinical trial.

Fact: Many cancer clinical trials take place at local hospitals. Some also take place at local cancer clinics and doctors' offices.

—Coalition of cancer cooperative groups

*Harris Interactive Survey, 2000

Additional Resources

For More Information

Alaska

Anchorage

**Alaska Regional Hospital
Cancer Care Center**
2741 DeBarr Road. Building c-414
Anchorage, AK 99508
Phone: (907)264-1579 or 264-1431
<http://www.alaskaregional.com>

**Alaska Clinical Research
Center, LLC**
1200 Airport Heights Drive, Suite 330
Anchorage, AK 99508
Phone: (907)276-1455
<http://www.centerwatch.com>

**Providence Cancer Center
Research Department**
3851 Piper Street
Anchorage, Alaska 99508
Phone: (907) 212-6871
Fax: (907) 212-3674
<http://www.providence.org/Alaska>

Fairbanks

Oncology Data Center
Fairbanks Memorial Hospital
1640 Cowles St. Suite 2
Fairbanks, Alaska 99701
Phone: (907)458-5458 or 4458
Toll Free: 1-888-678-5458
[http://www.bannerhealth.com/
Locations/Alaska/Fairbanks](http://www.bannerhealth.com/Locations/Alaska/Fairbanks)

Cancer Treatment Center
Cancer Treatment Center Entrance
1640 Cowles St. Suite 2
Fairbanks, AK 99701
Phone: (907) 458-5380
[http://www.bannerhealth.com/Services/
Cancer](http://www.bannerhealth.com/Services/Cancer)

Nationwide

**American Cancer Society Clinical
Trials Matching Service**
<http://www.cancer.org>
or 1-800-303-5691

**CenterWatch Clinical
Trials Listing Service**
<http://www.centerwatch.com/>

Clinical Connection
<http://www.clinicalconnection.com/>

**Coalition of Cancer
Cooperative Group**
<http://www.CancerTrialsHelp.org>

NCI's Clinical Trials Locator
[http://www.cancer.gov/clinical trials](http://www.cancer.gov/clinical_trials)

U.S. National Institutes of Health
<http://www.clinicaltrials.gov>



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Alaska Department of Health and Social Services
Division of Public Health
Section of Chronic Disease Prevention and Health Promotion
Comprehensive Cancer Control Program
& the Clinical Trials Work Group
Phone: 269-8092
December, 2009


ALASKA
Comprehensive Cancer Partnership

March 7, 2017

Representative Jason Grenn
State Capitol Room 418
Juneau, AK 99801

Re: HB 43

Representative Grenn,

On behalf of Premera Blue Cross Blue Shield of Alaska, I am writing to respectfully request amendments to HB 43, *an Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill*. We offer these amendments to improve clarity for the patient regarding both the associated cost impacts and insurance coverage that may not include an investigational drug, biological product, or device that has not been approved by the U.S. Food and Drug Administration. These suggestions are similar to provisions incorporated in legislation that has passed or is pending in other states.

Add a new section 5:

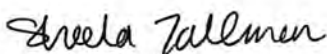
- (a) A health care insurer may, but is not required to, provide coverage for the cost of or the administration of an unapproved investigational drug, biological product, or device provided to a patient, and the patient may be required to pay the costs of administering the unapproved investigational drug, biological product, or device.
- (b) The patient's health care insurance plan is not required to pay, and may deny coverage, for an unapproved investigational drug, biological product, or device or the costs demonstrated to be associated with any harm or adverse effects caused to the patient that is a result of receiving the unapproved investigational drug, biological product, or device.
- (c) A health care insurer may not deny coverage to a patient for: (1) The patient's preexisting serious or immediately life-threatening disease or condition; (2) benefits that accrued before the day on which the patient was treated with an unapproved investigational drug, biological product, or device; or (3) palliative or hospice care for a patient who was previously treated with an unapproved investigational drug, biological product, or device but who is no longer being treated with an unapproved investigational drug, biological product, or device.

Section 1 (c) (2) defines terminal illness as a disease that will result in death in the near future. We recommend aligning the definition of terminal illness with Medicare, which considers an individual terminally ill if the medical prognosis is that the individual's life expectancy is six months or less.

"Terminal illness" means a stage of disease in which there is a reasonable likelihood that death will occur within six months or in which premature death is likely without early treatment [THAT, WITHOUT LIFE-SUSTAINING PROCEDURES, WILL RESULT IN DEATH IN THE NEAR FUTURE OR A STATE OF PERMANENT UNCONSCIOUSNESS FROM WHICH RECOVERY IS UNLIKELY].

Thank you for considering these suggestions to improve clarity. Please don't hesitate to get in touch with me if you have any questions.

Sincerely,



Sheela Tallman



Sheela Tallman
Senior Alaska Legislative Affairs Executive



House Bill 43: The Right to Try

Representative Jason Grenn



The Right to Try

"Patients should be free to exercise a basic freedom – attempting to preserve one's own life."

- Christina Corieri, Health Care Policy Analyst



House Bill 43

- **Sec. 1:** Prohibits disciplinary action by the State Medical Board, under specific patient terms. Provides key definitions.
- **Sec. 2:** Physicians, medical team members, manufacturers and distributors acting in good faith are not held liable, with proper informed consent and notification. Also not held liable for choosing not to participate.
- **Sec. 3:** Amends statute limiting the sale and distribution of new drugs to allow for physicians to prescribe and administer under conditions of Sec. 1.
- **Sec. 4:** Precludes hospitals and healthcare facilities from being required to provide increased services.

FDA Drug Review Process



Preclinical Animal Testing & Investigational New Drug (IND) Application



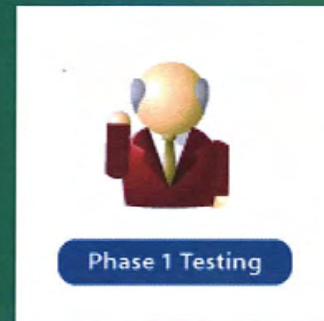
- Drug sponsors conduct preclinical testing in animals
- Upon IND application, results are reviewed
- FDA determines if drug is reasonably safe for human testing



FDA Drug Review Process (cont'd)

PHASE 1 - Safety

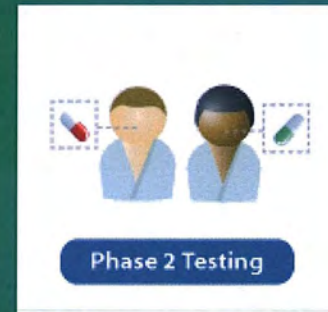
- Studies occur after approval of IND application
- Some conducted on healthy volunteers, but not all – depends on purpose of medication
- Determine side effects and toxicity levels



FDA Drug Review Process (cont'd)

PHASE 2 – Efficacy

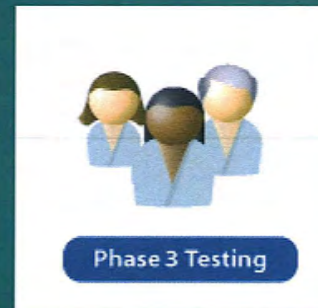
- Studies begin when drug is determined relatively safe
- Preliminary data on people with specific disease or condition
- Sets stage for scale of Phase 3 studies



FDA Drug Review Process (cont'd)

PHASE 3 – Comprehensive

- Studies begin if Phase 2 shows evidence of effectiveness
- Gather more info on safety and effectiveness
- Different dosages, populations and combination with other medications

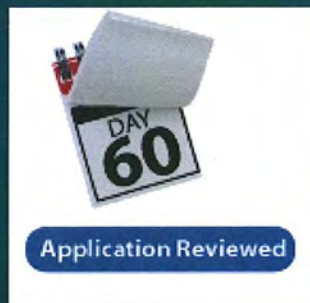


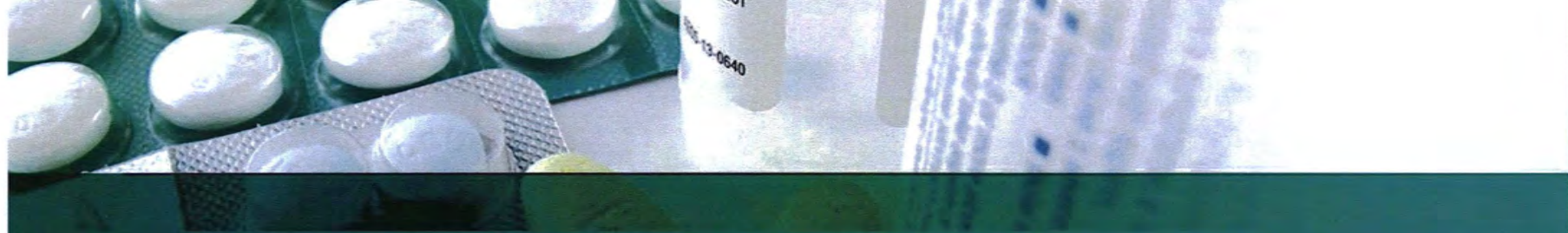
FDA Drug Review Process (cont'd)

Review Meeting & New Drug Application (NDA)



- Sponsors meet with FDA
- Submit NDA to officially request marketing approval
- FDA has 60 days to decide to file application
- 90% of applications are processed within 10 months of filing





An “*investigational drug, biological product, or device*” in HB 43 has completed Phase 1 and remains in ongoing clinical trials under Phase 2 or 3 or is in the marketing approval process, but is not yet available for general use



FDA's Expanded Access Program

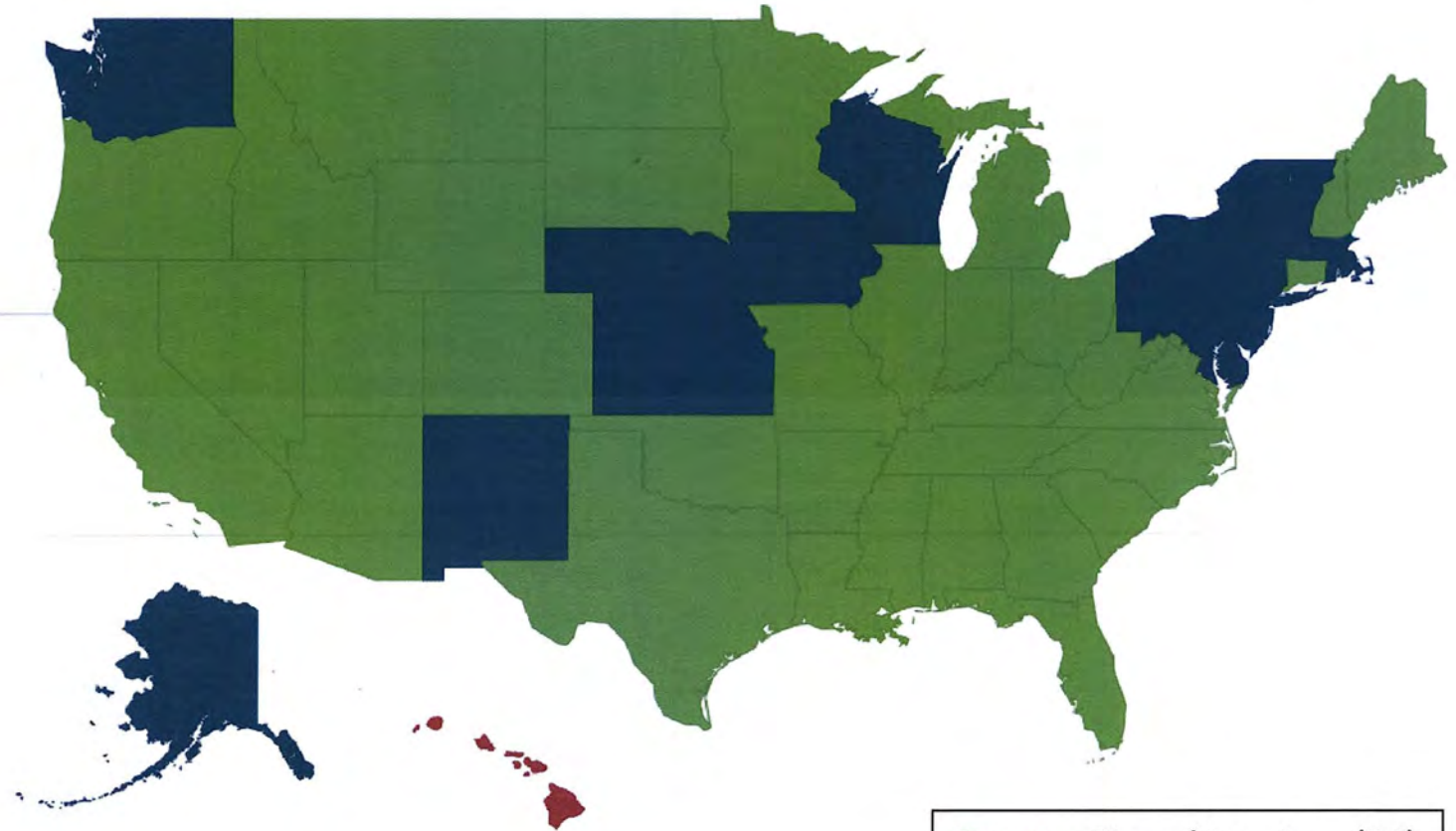
“Compassionate Use”

- Approx. 1,200 applicants per year make it through
- Application form has been streamlined, but approval process remains extensive




The Right to Try - A Nationwide Effort

All 50 states have passed or introduced "Right to Try" legislation



Green = Signed into Law (34)
Blue = Introduced (15)
Red = Vetoed (1)





This concludes our presentation
for House Bill 43.

Thank you.

